REMARKS

Applicants respectfully request reconsideration of the present Application. Claims 1, 3, 6, 7, 8, 10, 13, 14, 15, 17, and 19-21 have been amended herein. Claims 22 and 23 have been added by way of the present communication. Care has been exercised to introduce no new matter. Accordingly, claims 1, 3, 5-8, 10, 12-15, 17, and 19-23 are pending and are in condition for allowance.

Rejections based on 35 U.S.C. § 101

The United States Supreme Court has recognized that the expansive language of 35 U.S.C. §101 includes as statutory subject matter "anything under the sun that is made by man." *Diamond v. Chakrabarty*, 447 U.S. 303, 308-09 (1980). The USPTO has adopted the Supreme Court's interpretation and has stated that, in practice, the complete definition of the scope of 35 U.S.C. § 101 "is that any new and useful process, machine, manufacture or composition of matter under the sun that is made by man is the proper subject matter of a patent." MPEP 2106(IV)(A). More specifically, the MPEP states that "computer programs are often recited as part of a claim." MPEP 2106.01(I). In considering such claims, "USPTO personnel should determine whether the computer program is being claimed as part of an otherwise statutory manufacture or machine. In such a case, the claim remains statutory irrespective of the fact that a computer program is included in the claim." *Id.*; *see also In re Beauregard*, 53 F.3d 1582 (Fed. Cir. 1995). "The same result occurs when a computer program is used in a computerized process where the computer executes the instructions set forth in the computer program." MPEP 2106.01(I).

Claims 1, 3, 5-8, 10, 12-15, 17 and 19-21 stand rejected under 35 U.S.C. § 101 as being directed toward non-statutory subject matter. More specifically, claims 1, 3, 5-8, 10, 12-15, 17 and 19-21 stand rejected under 35 U.S.C. § 101 for failure to produce a tangible result. *See, Office Action* at p. 4. Also, claims 15, 17, and 19-21 were rejected 35 U.S.C. § 101 as including carrier waves. *Id.* Applicants respectfully submit that the following remarks and corresponding amendments overcome the rejection and, as such, Applicant's request withdrawal of the 35 U.S.C. § 101 rejection of claims 1, 3, 5-8, 10, 12-15, 17 and 19-21.

As amended herein, independent claim 1 is directed to a computer-implemented method for displaying on a user interface information regarding the likelihood a person has a gene variant indicative of an atypical event. Independent claim 8, as amended herein recites, a computer system embodied on one or more computer storage media having computer-executable instructions embodied thereon for displaying on a user interface information regarding the likelihood that the person has the gene variant indicative of an atypical event based on the hereditary information. Independent claim 15, as amended herein is directed to a computer-storage medium having computer-executable instructions embodied thereon for displaying on a user interface information regarding the likelihood that the person has the gene variant indicative of an atypical event based on the hereditary information

Applicants respectfully submit that independent claims 1, 8 and 15 as amended herein, are not directed to non-statutory subject matter. The Office Action indicates the 35 U.S.C. § 101 rejection could be overcome by amendment of the claims to recite that a result of the method is outputted to a display or to a user. *Id.* Amended claims 1, 8 and 15 produce a tangible result since said claims recite *displaying on a user interface* information regarding the likelihood a person has a gene variant indicative of an atypical event. As such, Applicants

respectfully request the 35 U.S.C. § 101 rejection of independent claims 1, 8 and 15 be withdrawn.

Furthermore, Applicants respectfully submit that "computer-storage media" as recited in amended independent claim 15 and defined in the specification excludes "carrier waves" and as such, the claim recites statutory subject matter. In particular, the Specification indicates that "computer-readable media" include "computer-storage media" that do not include signals. *See Specification* at ¶¶ [0025]-[0026]. As such, Applicants respectfully request the rejection of independent claim 15 under 35 U.S.C. § 101 be withdrawn.

Accordingly, for at least the above-cited reasons, it is respectfully requested that the 35 U.S.C. § 101 rejection of claims 1, 8 and 15 be withdrawn. Each of claims 3, 5-7, 10, 12-14, 17 and 19-21 depends, directly or indirectly, from either independent claim 1, 8 or 15. As such, each of dependent claims, 5-7, 10, 12-14, 17 and 19-21 incorporates the subject matter of amended independent claims 1, 8 and 15. *See,* 37 C.F.R. 1.75(c). Accordingly, it is respectfully requested that the 35 U.S.C. § 101 rejection of dependent claims 5-7, 10, 12-14, 17 and 19-21 be withdrawn at least by virtue of their dependency.

Rejections based on 35 U.S.C. § 103(a)

Title 35 U.S.C. § 103(a) declares, a patent shall not issue when "the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." The Supreme Court in *Graham v. John Deere* counseled that an obviousness determination is made by identifying: the scope and content of the prior art; the level of ordinary skill in the prior art; the differences between the

claimed invention and prior art references; and secondary considerations. *Graham v. John Deere Co.*, 383 U.S. 1 (1966).

To support a finding of obviousness, the initial burden is on the Office to apply the framework outlined in *Graham* and to provide some reason, or suggestion or motivation found either in the prior art references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the prior art reference or to combine prior art reference teachings to produce the claimed invention. *See*, *Application of Bergel,* 292 F. 2d 955, 956-957 (1961). Thus, in order "[t]o establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success [in combining the references]. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations." *See* MPEP § 2143. Recently, the Supreme Court elaborated, at pages 13-14 of *KSR*, it will be necessary for [the Office] to look at interrelated teachings of multiple [prior art references]; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by [one of] ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the [patent application]." *KSR v. Teleflex*, 127 S. Ct. 1727 (2007).

Claims 1, 3, 5-8, 10, 12-15, 17 and 19-21 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Ichikawa (Internal Medicine (July 2000) vol. 39, no. 7, pp. 523-524, hereinafter "the Ichikawa reference") in view of Reinhoff et al., (U.S. 2002/0049772, hereinafter "the Reinhoff reference"). As the asserted combination of references fails to teach or suggest all

of the limitations set forth in the rejected claims, Applicants respectfully traverse these rejections, as hereinafter set forth.

Independent claim 1 as amended herein is generally directed to a computer-implemented method, for displaying information on one or more user interfaces regarding the likelihood a person has a gene variant indicative of an atypical event. The method comprising the steps of, displaying a first user interface to a clinician, the user interface configured to display and receive clinical agent information including at least one identifier of a clinical agent, receiving from the user interface the clinician's inputs including at least one identifier of a clinical agent, accessing a data structure to determine if a gene variant is known to be associated with one or more atypical events for the clinical agent information, and inquiring if the person has a stored genetic test result value for the gene variant. The method is further comprised of accessing hereditary information for the person if the person does not have a genetic test result value for the genetic variant, the hereditary information being information that may be utilized to determine if the person has a predisposition for certain conditions, utilizing the hereditary information for the person to determine the likelihood the person has the gene variant, generating an output including information regarding the likelihood that the person has the gene variant indicative of an atypical event based on the hereditary information, and displaying a second user interface to the clinician, the user interface configured to display the output regarding the likelihood the person has the gene variant indicative of an atypical event based on the hereditary information. *See generally, Specification* at ¶¶[0032]-[0033], [0039], [0041]-[0042]; FIG. 3, FIG. 6.

By way of contrast with the invention of claim 1, the Ichikawa reference describes a method of genetic screening where a particular single nucleotide polymorphism may be used to

disclose severe side effects or proper dosage for a patient. *See generally, Ichikawa* at p. 523. The Ichikawa reference describes that a patient with an autosomal recessive trait for thiopurine S-methyl transferase (TMPT) deficiency may experience marked leucopenia when treated with immunosuppressants including azathioprine. *Id.* Applicants respectfully submit that the Ichikawa reference fails to teach or suggest multiple features of claim 1, 8 and 15. For instance, the Ichikawa reference fails to teach or suggest displaying a user interface to a clinician, where the user interface is configured to display and receive clinical agent information including an identifier of a clinical agent. The Ichikawa reference also fails to teach displaying a second user interface to the clinician, where the user interface is configured to display an output regarding the likelihood the person has the gene variant indicative of an atypical event based on the hereditary information.

The Office Action has acknowledged that the Ichikawa reference fails to teach the computer implemented aspects the invention of claim 1 including the aspect of accessing a data structure to determine if a gene variant is known to be associated with one or more atypical events. *See Office Action* at p. 7. The Office asserts that the Reinhoff reference teaches the above-mentioned features.

The Reinhoff reference is directed to a computer program product for separating individuals into subpopulations using a polymorphic profile in a networked environment. *See Reinhoff* at ¶ [0010]. In the Reinhoff reference, when a polymorphism is known to be associated with a response to a known treatment, this information may be used to allocate the most appropriate dose to subjects enrolled in a treatment study such as a clinical trial. *Id.* at ¶ [0057].

Applicants respectfully submit that the feature of displaying a user interface to a clinician, where the user interface is configured to display and receive clinical agent information

including an identifier of a clinical agent, as described in the invention of claims 1, is also absent from the Reinhoff reference. In addition, the Reinhoff reference fails to teach or suggest displaying a second user interface to the clinician, where the user interface is configured to display an output regarding the likelihood the person has the gene variant indicative of an atypical event based on the hereditary information. Rather, the Reinhoff reference discloses a computer program product that allows for comparing an individual's polymorphic profile with a plurality of polymorphic profiles to assist in performing clinical trials by ascertaining whether a particular nucleic acid variation affects the efficacy of a pharmaceutical. *Id.* at ¶¶ [0011]-[0014]. As such, there is no teaching or suggestion in the Reinhoff reference that an automated computer system may be used to display on a user interface information regarding the likelihood that the person has the gene variant indicative of an atypical event based on hereditary information.

The Reinhoff reference also fails to teach or suggest a method in a computer system for accessing hereditary information for the person if the person *does not have a genetic test result value* for the genetic variant, the hereditary information being information that may be utilized to determine if the person has a predisposition for certain conditions, as recited in independent claim 1. Instead, the Reinhoff reference describes a computer program product that allows for identification of a "susceptibility locus in individuals using genetic screening methods to assess an individual's risk of certain diseases." *Id.* at ¶ [0010]. The genetic screening methods in the Reinhoff reference consist of genetic tests involving using polymerase chain reaction (PCR) and other polymerase driven amplification assays to determine an individual's polymorphic profile. *See generally, id.* at ¶¶ [0027]-[0038]. The Reinhoff reference is silent on utilizing the hereditary information for the person to determine the likelihood the person has the

gene variant, in the absence of a genetic test. Accordingly, Applicants submit that the Ichikawa reference in view of the Reinhoff reference fails to teach or suggest all the limitations of the independent claim 1 and traverse this rejection.

Independent claims 8 and 15 as amended, include features similar to those discussed above with respect to independent claim 1. Independent claim 8, as amended herein recites a computer system embodied on one or more computer storage media having computer-executable instructions embodied thereon for displaying information on one or more user interfaces regarding the likelihood that the person has the gene variant indicative of an atypical event based on the hereditary information. The system comprising a first displaying component that displays a first user interface to a clinician, the user interface configured to display and receive clinical agent information including at least one identifier of a clinical agent, a receiving component that receives from the user interface the clinician's inputs including at least one identifier of a clinical agent, and a first accessing component for accessing a data structure to determine if a gene variant is known to be associated with one or more atypical events for the clinical agent information. *See generally, Specification* at ¶¶[0032]-[0033], [0039]; FIG. 3. The system further comprises an inquiring component that inquires if the person has a stored genetic test result value for the gene variant, a second accessing component for accessing hereditary information for the person if the person does not have a genetic test result value for the gene variant, the hereditary information being information that may be utilized to determine if the person has a predisposition for certain conditions, a utilizing component for utilizing the hereditary information for the person to determine the likelihood the person has the gene variant. *See generally, Specification* at ¶¶[0041]-[0047]. The system further comprises a generating component that generates an output including information regarding the likelihood that the

person has the gene variant indicative of an atypical event based on the hereditary information, and a second displaying component for displaying a second user interface to the clinician, the user interface configured to display the output regarding the likelihood the person has the gene variant indicative of an atypical event based on the hereditary information. *See generally, Specification* at ¶¶[0050]-[0052].

As amended herein, independent claim 15 is generally directed to a computer-storage medium containing instructions for a method for controlling a computer system for displaying information on one or more user interfaces regarding the likelihood that the person has the gene variant indicative of an atypical event based on the hereditary information. The method comprises displaying a first user interface to a clinician, the user interface configured to display and receive clinical agent information including at least one identifier of a clinical agent; receiving from the user interface the clinician's input including at least one identifier of a clinical agent; accessing a data structure to determine if a gene variant is known to be associated with one or more atypical events for the clinical agent information; and inquiring if the person has a stored genetic test result value for the gene variant. *See generally, Specification* at ¶¶ [0032]-[0033], [0039]; FIG. 3. The method further comprises accessing hereditary information for the person if the person does not have a genetic test result value for the genetic variant, the hereditary information being information that may be utilized to determine if the person has a predisposition for certain conditions, utilizing the hereditary information for the person to determine the likelihood the person has the gene variant, generating an output including information regarding the likelihood that the person has the gene variant indicative of an atypical event based on the hereditary information, and displaying a second user interface to the clinician, the user interface configured to display the output regarding the likelihood the person has the

gene variant indicative of an atypical event based on the hereditary information. *See generally, Specification* at ¶¶ [0039], [0041]-[0042], [0050-0052]; FIG. 3, FIG. 6.

Similarly to the invention of claim 1, the invention of independent claims 8 and 15 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over the Ichikawa reference in view of the Reinhoff reference. Applicants respectfully traverse these rejections. Claims 8 and 15 as amended herein, include features similar to those discussed above with respect to independent claim 1. Applicants respectfully submit that the feature of displaying a user interface to a clinician, where the user interface is configured to display and receive clinical agent information including an identifier of a clinical agent, as described in the inventions of claims 8 and 15, is absent from the Reinhoff reference and the Ichikawa reference and as such, and for the other reasons discussed above, claims 8 and 15 are patentable over the Ichikawa and Reinhoff references. Further, as claims 5-7, 10, 12-14, 17 and 19-21 depend directly or indirectly from amended independent claims 1, 8 and 15, Applicants request withdrawal of the rejection of these claims as well.

CONCLUSION

For at least the reasons stated above, claims 1, 3, 5- 8, 10, 12-15, 17, and 19-23 are now in condition for allowance. Applicants respectfully request withdrawal of the pending rejections and allowance of the claims. If any issues remain that would prevent issuance of this application, the Examiner is urged to contact the undersigned – 816-474-6550 or ddevers@shb.com (such communication via email is herein expressly granted) – to resolve the same.

REQUEST FOR EXTENSION OF TIME

It is hereby requested that the time period for responding to the outstanding Office Action mailed July 24, 2008, be extended for one month or until November 24, 2008. The Petition fee of $130.00 is being submitted simultaneously with this paper by way of electronic payment.

In the event it is determined necessary, the Commissioner is hereby authorized to charge any additional fee which may be required, or credit any overpayment, to Deposit Account No. 19-2112.

Respectfully submitted,

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